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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, Maryland 20740

MAY - 4 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

President
KNL Pharmaceutical Company, Ltd.
58 Hicks Lane
Great Neck, New York 11024

Dear Sir:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.knlusa.com. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your product Cancerfx170 (also known as Canserfx170).[1] You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. Your web site claims that your product, which is labeled as a dietary supplement, is useful in the treatment, mitigation, cure, and prevention of cancer.

Your web site makes the following claims for Cancerfx170:

"A Safe Herbal Cancer Treatment is here."
"Treat Cancer, Naturally With Cancerfx170"
"Canserfx170 is an anti-cancer herb formula"

"[M]ajor functions of Canserfx170:"
"Anti-gene mutation, used to hinder cancer cell growth and accelerate the elimination of the cancer cells."
"[R]everts cancer cells back to normal cells."
"Reduce the side effects and promote response to radiation/chemotherapy."
"Significant[sic] increase cell immunity... in order to kill cancer cells."

These claims cause your product to be a drug, as defined in section 201(g)(1)(B) of the Act. Because the product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

[1] Your website sometimes identifies the product as "Cancerfx170" and sometimes as "Canserfx170."

Even if your product Cancerfx170 did not contain disease claims in its labeling that cause it to be a drug, it would still be misbranded as a dietary supplement. Your web site (http://www.knlusa.com/productcart/pc/fda.asp) contains a copy of a Certificate of Free Sale issued by FDA for Cancerfx170.

The Certificate states in general terms that your product is regulated by FDA and that it may be freely marketed in the U.S. or exported, provided that it conforms to all applicable U.S. laws and regulations. The Certificate further states that (even if a product does not conform to all applicable U.S. laws and regulations and may not be marketed domestically) the product may nevertheless be exported if it meets the specifications of section 801(e) of the Act. The Certificate expressly states that FDA did not examine Cancerfx170 or review its label. Accordingly, the Certificate is not a guarantee or certification that Cancerfx170 conforms to the applicable U.S. laws and regulations or that it may be legally exported under section 801(e).

The web site also contains an excerpt from Title 21, Code of Federal Regulations, Section 5.22 ((21 CFR 5.22), a regulation pertaining to the certification of true copies of FDA documents and the use of the Department of Health and Human Services seal. This regulation lists the FDA officials who are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the FDA, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the non-existence of records on file within the FDA, and to cause the seal of the Department of Health and Human Services to be affixed to such certifications. This regulation has absolutely no bearing on the regulatory status of your product.

The documents described above are displayed along with pictures of product containers of Canserfx170 in a manner that suggests that FDA has approved or otherwise sanctioned the marketing of your product and, implicitly, the representations you are making for it elsewhere on your web site. Your product is not approved by FDA, nor has FDA reviewed its formulation or the representations made for it. Therefore, the use of this information in the manner you display it in the promotion of your product is false or misleading in that it implies FDA approval or sanction of your product and its purported uses. This misleading information misbrands your product under section 403(a)(1) of the Act.

The violations described above are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure

that similar violations do not occur. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

You should direct your reply to Kristen Moe, Compliance Officer, at 5100 Paint Branch Parkway (HFS-607), College Park, MD. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition